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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/516,897	07/05/2005	Manne Satyanarayana Reddy	BULK 3.3-017 U.S.	1563

45776 7590 12/12/2007

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EXAMINER	
HAVLIN, ROBERT H	
ART UNIT	**PAPER NUMBER**
1626	

MAIL DATE	DELIVERY MODE
12/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/516,897	REDDY ET AL.	
	Examiner	Art Unit	
	Robert Havlin	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *26 October 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24,27-30 and 36-47* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-24, 27-30, 36-47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the claims: Claims 1-24, 27-30, and 36-47 are currently pending.

Priority: As indicated in the prior office action, the priority date is the filing date.

IDS: The IDS dated 7/19/07 was considered.

Rejections

102(b) rejection over Oxford

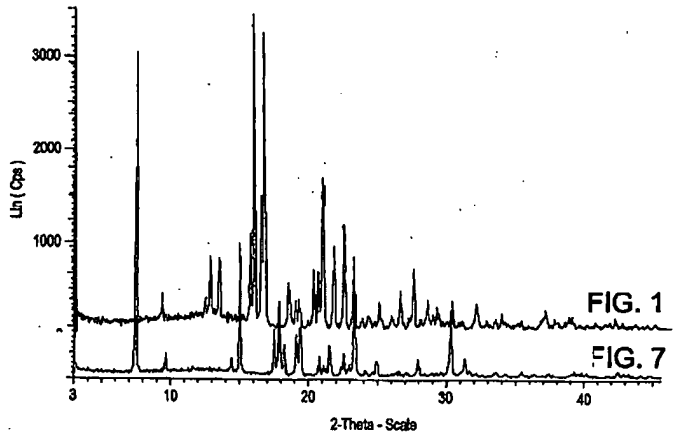
The applicant argues that the solvents used are different from Oxford and that the subject matter has not been shown to be necessarily present.

The examiner believes the product of the instant invention is anticipated by Oxford because they have the identical chemical formula, and the only distinguishing characteristic is that the process by which the product is isolated (using somewhat different solvents). But this argument fails because the 102(b) rejection is only for the products and limitations of the methods used to produce the product are not relevant.

Thus, the claims attempt to distinguish from the prior art by citing X-ray powder diffraction patterns, differential scanning calorimetry (DSC) data, and infra-red (IR) data. However, nowhere is the instantly claimed subject matter directly compared with the prior art teachings of Oxford.

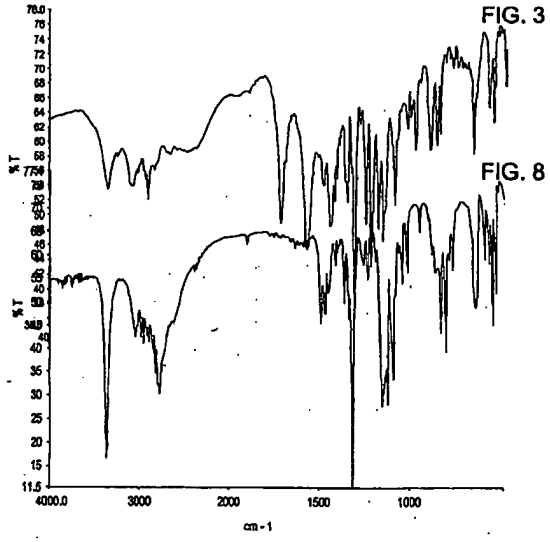
The applicant includes the drawings of figure 1 and 7 apparently to allow for comparison of "a sample of crystalline Form-I of present invention" (figure 1) with "an example of XRD pattern of a sample of a highly pure Sumatriptan" (figure 7). But, the specification does not indicate the precise molecular structure of the "example of" "a sample of a highly pure Sumatriptan", conspicuously omitting whether "a highly pure"

actually refers to the succinate salt of the instant invention. Regardless, the examiner below has attempted to compare the only data he has available (since the PTO does not have a laboratory to conduct experiments which could easily prove or disprove anticipation in this case):



Examination of the above figure and taking into account the possibility of impurities (no mention of the purity level in FIG 1) and alternate salt forms (is FIG. 7 succinate?) the X-ray data actually appears to identify the same compounds. According to this comparison, the possibility for different conditions, and the examiner's familiarity with X-ray powder diffraction comparisons of compounds, he has concluded that the above shown overlapping peaks are a rational basis to conclude that the teachings of Oxford would anticipate the claims. *See generally* H. G. Brittain, "Polymorphism in Pharmaceutical Solids" *in* Drugs in the Pharmaceutical Sciences pp. 427, vol. 95, 1999, Marcel Dekker: New York; S. R. Byrn, et al., Solid-State Chemistry of Drugs, second edition, pp. 576, 1999, SSCI: West Lafayette, Indiana.

This conclusion is buttressed by the comparison of the IR data below taking into account the same purity and salt issues:



Again, the above comparison of the IR data shows that the two samples have substantially the same structure when taking into account the aforementioned issues of the possibility that the samples may contain impurities or other salts. Therefore, shifting the burden to applicant to prove Oxford does not anticipate the claims was and remains appropriate.

Similarly, the same analysis holds for "Form-II" of sumatriptan succinate.

The rejection under 102(b) of claims 1-7, 13-20, 29-30, 42-44 and 45 is maintained.

103(a) rejection

The applicant argues that a reasonable expectation of success in finding the specific polymorph claimed in view of the prior art does not exist.

Again, the only apparent difference in the product produced by the process claimed in the instant application is the use of a solvent other than industrial methylated spirits (IMS as indicated in Oxford). IMS is actually a mixture primarily of ethanol with methanol added and one of ordinary skill in the art is aware that it is a good crystallization solvent. Thus one of ordinary skill in the art immediately would know to look to alternate solvents. Furthermore, one of ordinary skill in the art would be also motivated by teachings such as Brittain to produce a crystalline product with optimal bioavilability using the solvents suggested therein. In fact, claim 8 produces the "Form-I" of the compound using any of the following solvents (IMS would read on claim 8 if ethanol was not omitted):

> acetone, methyl isobutyl ketone, methyl ethyl ketone, tetrahydrofuran, diethyl ether, diisopropyl ether, diisobutyl ether, methyl acetate, ethyl acetate, propyl acetate, butyl acetate, methanol, propanol, isopropanol, butanol, isobutanol, and mixtures thereof

many of which are taught by Brittain. Because, one of skill in the art would reasonably be expected to consider using alternate solvents such as those recited above to recrystallize the product, there is a reasonable expectation of success that one of ordinary skill in the art would take one of the alternate solvents suggested by Brittain or generally known in the art as being good for crystallization and routinely optimize the product to produce the product with the best solid state characteristics for use as originally taught by Oxford. Restated, the claims would have been obvious because the substitution of one known solvent for another to routinely optimize the product's same utility would have been predictable to one of ordinary skill in the art at the time of the invention.

Thus, the examiner maintains rejection of claims 1-24, 27-30, 36-47 under 35 USC 103(a).

112 rejections

The 112 rejections of claims 1-8, 12-20, 24, 27, 29, 30, and 40-42 are withdrawn. Applicant's arguments are persuasive as to the enablement and definiteness of the subject matter.

Conclusion

All claims are rejected. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Havlin whose telephone number is (571) 272-9066. The examiner can normally be reached on Mon. - Fri., 7:30am-5pm EST.

If attempts to reach the examiner by telephone are unsuccessful the examiner's supervisor, Joe McKane can be reached at (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Robert Havlin
Examiner

RH

KAMAL A. SAEED, PH.D.
PRIMARY EXAMINER